SEAFOOD HACCP TRANSITION GUIDANCE

Guidance for Industry and CFSAN Staff

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Office of Seafood

Document Issued on : December 1999

Additional Copies: World Wide Web/ CFSAN home page at http://vm.cfsan.fda.gov/~dms/guidance.html **or from the Industry Activities Staff, Office of Constituent Operations, Center for Food Safety and Applied Nutrition, 202-205-5251.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Washington, DC 20204

SEAFOOD HACCP TRANSITION GUIDANCE

A. Purpose of the Guidance

This guidance outlines a procedure for requesting FDA to consider exercising enforcement discretion on certain matters under the seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR part 123) pending the scientific resolution of issues bearing on food safety hazards. This guidance applies to issues involving matters of scientific fact related to whether a hazard is reasonably likely to occur or whether a control is sufficient, the resolution of which is likely only after the completion of a scientific study or a search of existing scientific literature.

B. Background Information

On December 18, 1995 (60 FR 65096), FDA published final regulations (21 CFR part 123) that require processors of fish and fishery products to develop and implement HACCP systems for their operations. Those regulations became effective on December 18,1997. As a companion to the regulation, FDA also issued a guidance document entitled the Fish and Fishery Products Hazards and Controls Guide (the Guide). The Guide contains FDA's compilation of what the agency believes to be the latest, science-based knowledge about when food safety hazards are reasonably likely to occur and what controls are appropriate for those hazards. In the period since the publication of the final regulations, FDA has produced two editions of the Guide.

Under the Federal Food, Drug, and Cosmetic Act and its implementing regulations, processors are responsible for ensuring that their HACCP systems are adequate. If processors need help in developing a HACCP

system, the Guide provides them with information that can help them put in place a HACCP system that should generally satisfy a processor's obligations under the seafood HACCP regulation. However, as the Guide itself makes clear, the materials contained in the Guide consist of recommendations, and not binding requirements. Processors may control hazards in other ways so long as they can demonstrate that their approaches are scientifically defensible. Processors may also rely on hazard analyses that differ from those in the Guide so long as they can demonstrate that their own analyses are valid for their particular circumstances. As a general matter, processors should establish the adequacy of a hazard analysis or control before implementing it.

FDA can envision circumstances, however, where the industry could make a strong threshold case for the validity of a particular hazard analysis or system of controls even though complete confirmation of its validity was not yet available from scientific studies. FDA believes that a mandatory HACCP program should serve as a catalyst for research and science-based resolution of food safety questions. Thus, where the consuming public would not be placed at risk, FDA believes it is appropriate to use a mechanism that encourages the resolution of legitimate scientific questions before they become legal controversies.

C. Scope and Recommended Procedure

The purpose of this guidance is to assist interested parties with the submission of a citizen's petition under 21 CFR 10.30, whereby any member of the public may request that FDA consider exercising enforcement discretion on certain matters under the seafood HACCP regulations pending their scientific resolution. This proposed guidance applies to issues involving matters of scientific fact related to whether a hazard is reasonably likely to occur or whether a control is sufficient, the resolution of which is likely only after the completion of a scientific study or a search of existing scientific literature. Other issues that relate to broader policy, such as circumstances where regulations, rather than

guidelines, specify hazards that are reasonably likely to occur in certain situations or enumerate performance standards or the actual critical limits that must be met, may also be addressed by filing a citizen's petition, or by discussing the issue directly with the agency in a less formal manner, but are not within the scope of this guidance.

FDA anticipates that matters for which limited enforcement discretion will be considered will be narrow. In determining whether to exercise enforcement discretion, the agency may consider, among other things, whether the position presented by the petitioner has sufficient scientific merit and whether the petitioner's proposal is appropriate and adequate to answer the necessary scientific questions (e.g., whether the study and/or literature search that will be undertaken will, in the agency's judgment, provide the information needed to support the requested change; whether the identification of the time necessary to complete the study and any data analysis is reasonable; whether the petitioner commits to keeping FDA apprised of the progress being made on the study plan over the course of the study; and whether the petitioner agrees to provide FDA with all data from the study in order to advance the public state of knowledge, regardless of the outcome of the study). FDA does not anticipate that, under ordinary circumstances, economic or environmental assessments will be relevant to the question of enforcement discretion. FDA recommends that such petitions be submitted as requests to revise or amend the Guide. If a party believes that the Guide should be revised based on scientific data to be provided at a later date, the party should submit a petition under Sec. 10.30 to the Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

In addition, interested persons are encouraged to discuss the contents of an intended petition in advance of submission with representatives of FDA's Office of Seafood either in person or by telephone (202-418-3133). Such communication may minimize misunderstandings and time-consuming written communication during the consideration process.

FDA may, at its discretion, consult with scientific experts outside the agency, including existing advisory committees, during the review of the petition.

If FDA determines, after reviewing a request, that it is appropriate for the agency to exercise enforcement discretion, the agency will advise the requester in writing that the agency does not anticipate enforcement action for the practice at issue and will post the letter on its Internet web site at ``http://www.fda.gov". FDA will also advise the requester of the time period that the agency believes is reasonable for the study and data analysis. If, at the end of this time frame, the agency concludes that the data from the study are inadequate, or if no data are submitted, FDA will proceed with its regulatory options.

The agency may also reconsider the use of enforcement discretion before the end of the timeframe if circumstances change or otherwise warrant reconsideration. If such reconsideration takes place, FDA will notify the original requester and make its reconsideration public.

In considering the information submitted at the conclusion of the study, FDA will evaluate, as appropriate: (1) The methodology of the scientific study; (2) the scientific merit of the conclusions; and (3) the consistency of the recommended action with agency policy. When considering the adequacy of scientific detail presented in the study, FDA expects to take into account the severity of the hazard at issue and the extent and credibility of available data that must be overcome in order for the agency to integrate the petitioner's recommendation into its own guidelines. As part of its review of the results of the study, the agency may, at its discretion, consult with scientific experts outside the agency, including existing advisory committees. Any changes in agency position will be posted on FDA's Internet website at ``http://www.fda.gov" and then reflected in the next edition of the Guide.

The public is reminded that it is welcome to discuss with the agency at any time issues relating to seafood hazards and controls and how these issues may be resolved through research.

The agency expects that it will keep the public apprised of the existence and status of any petitions received under this guidance. FDA is especially aware of the importance of this information to states that may be contemplating enforcement actions of their own on matters relevant to a petition.

This guidance represents the agency's current thinking on the subject and does not create or confer any rights for or on any person and does not operate to bind FDA or the public.